



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

April 7, 2004

Mr. James N. Czaban
Heller Ehrman White & McAuliffe LLP
1666 K Street, N.W.
Washington, D.C. 20006

FILE COPY

Dear Mr. Czaban:

Your petition for stay of action submitted on behalf of Mutual Pharmaceutical Co., Inc. requesting the Food and Drug Administration to stay any final approval of NDA 13-217/S-046, or any other labeling supplement for skelaxin (metaxalone) tablets, was received by this office on 04/05/2004. It was assigned docket number 2004P-0140/PSA 2 and it was filed 04/06/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2004P-0140

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